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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10.042,815	01.08.2002	Rebecca Rose	4018-1-CON-1	7686

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EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/18/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/042,815

Applicant(s)

ROSE ET AL.

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 25-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_ 6) ☐ Other: \_\_\_\_

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### **DETAILED ACTION**

1. The preliminary amendment filed January 8, 2002 has been received and entered.
2. Claims 1-24 have been cancelled.
3. Claims 25-33 are pending.

### ***Claim Objections***

Claims 31 and 33 are objected to because of the following informalities: "turmeric" is misspelled as "tumeric." Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. These claims are indefinite because the meaning of term "metabolic precursor" in claims 31 and 32 and the meaning of "precursor" in claim 33 is unclear.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

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A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 25-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,344,220 B1.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of both sets of claims overlaps. The present claims are directed towards a composition that "comprises" all of the same ingredients that are claimed in US '220. Therefore, the scope of the claims overlaps.

5. Claims 25-30 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 5,916,565. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of both sets of claims overlaps. The present claims are directed towards a composition that "comprises" the same ingredients that are claimed in US '565. Therefore, the scope of the claims overlaps. The present claims are also not identical in scope to the claims of US '565 because the composition in claim 1 of US '565 contains a palatability agent that is not present in the present claims. Although the conflicting claims are not identical, they are not patentably distinct from each other because a person of ordinary skill in the art would recognize that the palatability agent is not an active ingredient in the composition of US '565. Thus, an artisan of ordinary skill would reasonably expect that the composition of US '565 would function as

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effectively without the palatability agent. A person of ordinary skill in the art would have been motivated to modify the composition of claim 1 in US '565 to exclude the palatability agent.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. Claims 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirschhorn (*The Home Herbal Doctor* (1982), Parker Publishing Company, Inc.: New York, pp. 50-51), Hobbs (*Handbook for Herbal Healing* (January 1995), Botanica Press: California, pp. 62 and 63), Castleman (*Healing Herbs* (1991), Rodale Press: Pennsylvania, pp. 37-39, 186-189, and 355-357), US Pat. No. 5,364,845, and US Pat. No. 3,887,703.

The claims are drawn to a composition that contains devil's claw, alfalfa, yucca, ginger, turmeric, and a metabolic precursor selected from glucosamine, chondroitin, or mucopolysaccharides.

Hirschhorn teaches using devil's claw to treat arthritis (see page 50, first paragraph).

Hobbs teaches that yucca and turmeric have antiinflammatory activity and can be used in a preparation to treat arthritis.

Castleman teaches that alfalfa can be used to treat arthritis (see page 37). Castleman also teaches using ginger to treat arthritis (see page 188). In addition, Castleman teaches that turmeric can be used to treat arthritis (see page 356).

US '845 teaches using glucosamine and chondroitin to treat arthritis (see claims and column 1, lines 15-23).

US '703 teaches using mucopolysaccharides to treat arthritis (see column 14, lines 8-20).

These references show that it was well known in the art at the time of the invention to use devil's claw, alfalfa, yucca, ginger, turmeric, and a metabolic precursor such as glucosamine, chondroitin, or mucopolysaccharides in arthritis treating compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

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Based on the disclosure by these references that these substances are used in arthritis treating compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating an arthritis treating compositions. Therefore, the artisan would have been motivated to combine devil's claw, alfalfa, yucca, ginger, turmeric, and a metabolic precursor such as glucosamine, chondroitin, or mucopolysaccharides into a composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

7. Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hobbs (*Handbook for Herbal Healing* (January 1995), Botanica Press: California, pp. 62 and 63), Castleman (*Healing Herbs* (1991), Rodale Press: Pennsylvania, pp. 37-39, 186-189, and 355-357), US Pat. No. 5,364,845, and US Pat. No. 3,887,703.

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The claims are drawn to a composition that contains alfalfa, yucca, ginger, turmeric, and a metabolic precursor selected from glucosamine, chondroitin, or mucopolysaccharides.

Hobbs teaches that yucca and turmeric have antiinflammatory activity and can be used in a preparation to treat arthritis.

Castleman teaches that alfalfa can be used to treat arthritis (see page 37). Castleman also teaches using ginger to treat arthritis (see page 188). In addition, Castleman teaches that turmeric can be used to treat arthritis (see page 356).

US '845 teaches using glucosamine and chondroitin to treat arthritis (see claims and column 1, lines 15-23).

US '703 teaches using mucopolysaccharides to treat arthritis (see column 14, lines 8-20).

These references show that it was well known in the art at the time of the invention to use alfalfa, yucca, ginger, turmeric, and a metabolic precursor such as glucosamine, chondroitin, or mucopolysaccharides in arthritis treating compositions. It is well known that it is prima facie obvious to combine two or more ingredients each of which is taught by the prior art to be useful for the same purpose in order to form a third composition which is useful for the same purpose. The idea for combining them flows logically from their having been used individually in the prior art. In re Pinten, 459 F.2d 1053, 173 USPQ 801 (CCPA 1972); In re Susi, 58 CCPA 1074, 1079-80; 440 F.2d 442, 445; 169 USPQ 423, 426 (1971); In re Crockett, 47 CCPA 1018, 1020-21; 279 F.2d 274, 276-277; 126 USPQ 186, 188 (1960).

Based on the disclosure by these references that these substances are used in arthritis treating compositions, an artisan of ordinary skill would have a reasonable expectation that a combination of the substances would also be useful in creating an arthritis treating compositions.



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Therefore, the artisan would have been motivated to combine alfalfa, yucca, ginger, turmeric, and a metabolic precursor such as glucosamine, chondroitin, or mucopolysaccharides into a composition. No patentable invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients. See *In re Sussman*, 1943 C.D. 518; *In re Huellmantel* 139 USPQ 496; *In re Crockett* 126 USPQ 186.

The references do not specifically teach adding the ingredients in the amounts claimed by applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of applicant's invention.

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

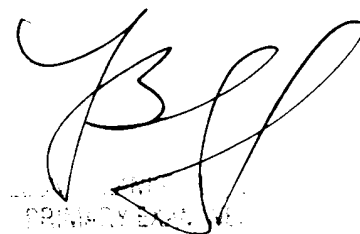
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SDC

June 13, 2002



Handwritten signature, possibly reading "B. L.", with a faint "PRINCE" stamp visible below it.